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<b>UTILITY PATENT APPLICATION TRANSMITTAL</b> <i>(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))</i>	Attorney Docket No.	PRES06-00163
	First Inventor or Application Identifier	Schachar, Ronald A.
	Title	SEGMENTED SCLERAL BAND FOR TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS
	Express Mail Label No.	EJ033593156US

<b>APPLICATION ELEMENTS</b> <i>See MPEP chapter 600 concerning utility patent application contents.</i>	<b>ADDRESS TO:</b> Assistant Commissioner for Patents Box Patent Application Washington, DC 20231
1. <input checked="" type="checkbox"/> * Fee Transmittal Form (e.g., PTO/SB/17) <i>(Submit an original and a duplicate for fee processing)</i>	5. <input type="checkbox"/> Microfiche Computer Program (Appendix)
2. <input checked="" type="checkbox"/> Specification [Total Pages <u>29</u> ] <i>(preferred arrangement set forth below)</i> - Descriptive title of the Invention - Cross References to Related Applications - Statement Regarding Fed sponsored R & D - Reference to Microfiche Appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings (if filed) - Detailed Description - Claim(s) - Abstract of the Disclosure	6. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) a. <input type="checkbox"/> Computer Readable Copy b. <input type="checkbox"/> Paper Copy (identical to computer copy) c. <input type="checkbox"/> Statement verifying identity of above copies
3. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets <u>4</u> ]	<b>ACCOMPANYING APPLICATION PARTS</b> 7. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) 8. <input type="checkbox"/> 37 C.F.R. § 3.73(b) Statement <input type="checkbox"/> Power of Attorney <i>(when there is an assignee)</i> 9. <input type="checkbox"/> English Translation Document (if applicable) 10. <input type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations 11. <input checked="" type="checkbox"/> Preliminary Amendment (w/redlined Spec and Substitute Spec) 12. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) <i>(Should be specifically itemized)</i> 13. <input type="checkbox"/> * Small Entity Statement(s) <input type="checkbox"/> Statement filed in prior application, Status still proper and desired <i>(PTO/SB/09-12)</i> 14. <input type="checkbox"/> Certified Copy of Priority Document(s) <i>(if foreign priority is claimed)</i> 15. <input checked="" type="checkbox"/> Other: Letter to Official Draftsman
4. Oath or Declaration [Total Pages <u>2</u> ] a. <input type="checkbox"/> Newly executed (original or copy) b. <input checked="" type="checkbox"/> Copy from a prior application (37 C.F.R. § 1.63(d)) <i>(for continuation/divisional with Box 16 completed)</i> i. <input type="checkbox"/> <u>DELETION OF INVENTOR(S)</u> Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).	
* NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).	

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:  
☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No: 09 / 032,830  
 Prior application information: Examiner Michael J. Milano Group / Art Unit: 3738  
 For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

**17. CORRESPONDENCE ADDRESS**

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Signature	<i>William A. Munck</i>	Date	April 21, 2000

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of : Ronald A. Schachar  
U.S. Serial No. : to be assigned  
Filing Date : to be assigned  
Prior U.S. Serial No. : 09/032,830  
Prior Filing Date : March 2, 1998  
Prior Examiner : Michael J. Milano  
Prior Group Art Unit : 3738  
Title : SEGMENTED SCLERAL BAND FOR  
TREATMENT OF PRESBYOPIA AND OTHER  
EYE DISORDERS

Assistant Commissioner of Patents  
Box Patent Application  
Washington, D.C. 20231

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<u>LAURA ZAVALA</u> Printed Name of Person Mailing	<u>EJ635935605</u> Express Mail Receipt No
<u>[Signature]</u> Signature of Person Mailing	<u>4-21-00</u> Date

Sir:

**PRELIMINARY AMENDMENT**

The Applicant is filing a continuing prosecution application under 37 C.F.R. § 1.53(b). Additionally, the Applicant is making the below listed amendments to the continuing application as follows:

IN THE SPECIFICATION

1. Please amend the following statement on page 1 under the section “RELATIONSHIP TO OTHER APPLICATIONS” of the specification:

“This application is a continuation of prior U.S. Application Serial No. 09/032,830 filed on March 2, 1998, which [This application] is a continuation-in-part of copending application Serial No. 08/462,649 filed June 05, 1995, now U.S. Patent No. 5,722,952, which is a divisional of U.S. application Serial No. 08/139,756, filed, October 22, 1993, now U.S. Patent No. 5,489,299, which is a divisional of U.S. application Serial No. 07/913,486, filed on July 15, 1992, now U.S. Patent No. 5,354,331”.

Please delete the existing specification beginning at page 1, section “BACKGROUND OF THE INVENTION” and ending on page 21. A copy of the marked-up specification showing the deleted sections is attached.

Please insert the new substitute specification pages beginning at page 1, with the section “BACKGROUND OF THE INVENTION” per the attached new specification pages 1-33.

IN THE CLAIMS

Please delete claims 2-30.

Please add new claims 31-44 as follows:

31. (New ) A laser operable to weaken the sclera of an eye in the region of the ciliary body to thereby increase the effective working distance of the ciliary muscle of the eye.

32. (New) The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by abrading the sclera with laser irradiation.

33. (New) The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by ablating the sclera with laser irradiation.

34. (New) The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by incising the sclera with laser irradiation.

35. (New) The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by incising the sclera at select angles with laser irradiation.

36. (New) The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by decomposing partially collagen fibers in the sclera.

37. (New) The laser set forth in Claim 31 wherein said laser is one of a carbon dioxide laser, a helium-neon laser, a helium-cadmium laser, an argon ion laser, a krypton ion laser, a xenon laser, a nitrous oxide laser, iodine laser, a holmium doped yttrium-aluminum garnet laser, an excimer laser, a chemical laser, a harmonically oscillated laser, a dye laser, a nitrogen laser, a neodymium laser, an erbium laser, a ruby laser, a titanium-sapphire laser and a diode laser.

38. (New) The laser set forth in Claim 31 wherein said laser uses one of ionizing radiation and non-ionizing radiation to weaken the sclera of an eye in the region of the ciliary body,

thereby increasing the effective working distance of the ciliary muscle of the eye.

39. (New) The laser set forth in Claim 31 operable to increase the amplitude of accommodation of the eye.

40. (New) A method of operating a laser to treat one of presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension, said method comprising the step of irradiating the sclera of an eye in the region of the ciliary body to thereby weaken the sclera of the eye and increase the effective working distance of the ciliary muscle of the eye.

41. (New) The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of abrading the sclera with laser irradiation.

42. (New) The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of ablating the sclera with laser irradiation.

43. (New) The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of incising the sclera

with laser irradiation.

44. (New) The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of decomposing partially collagen fibers in the sclera.

#### IN THE ABSTRACT

Please amend the Abstract as follows:

[A segmented scleral expansion band adapted for implantation within or fastening to a segment of the sclera of an eye lying outside of and adjacent to the ciliary body of the eye, is formed from a number of arcuate segments, curved to match the curvature of the globe of the eye, and joined together at each end to form a complete scleral expansion band. The band is implanted in the sclera of the eye by forming circumferential tunnels, inserting the band segments through the tunnels, and joining the ends of the segments to form a complete scleral expansion band. The scleral expansion band is useful in treating p] Presbyopia and other ocular disorders are treated by a method which increases the amplitude of accommodation by increasing the effective working distance of the ciliary muscle in the presbyopic eye. The effective working distance of the ciliary muscle can be increased by expanding the sclera in the region of the ciliary body. This expansion may be accomplished by operating a laser to irradiate the sclera of an eye in the region of the ciliary body to thereby weaken the sclera of the eye and increase the effective working distance of the ciliary muscle

of the eye.

### IN THE DRAWINGS

The Applicant is submitting new drawings (Figure 1-11) to replace the existing drawings in a separate letter to the Official Draftsman.

### REMARKS

Claims 2-30 have been deleted.

Claims 31-44 have been added.

Claims 1 and 31-44 remain in the application.

The Applicant is submitting a substitute specification attached hereto. A redlined version of the specification to be deleted is also attached. Pursuant to 37 C.F.R. § 1.125(b), the Applicant states that no new subject matter has been included in the substitute specification.

As stated above, this application is a continuation of co-pending United States patent application serial no. 09/032,830 filed on March 2, 1998 (the “830 Application”). The ‘830 Application is a continuation-in-part of then co-pending patent application serial no. 08/462,649 filed June 05, 1995, now United States patent no. 5,722,952 (the “649 Application”). The ‘649 Application was a co-pending divisional of United States patent application serial no. 08/139,756, filed, October 22, 1993, now U.S. Patent No. 5,489,299 (the “756 Application”). The ‘756 Application was a co-pending divisional of United States patent application Serial No. 07/913,486,



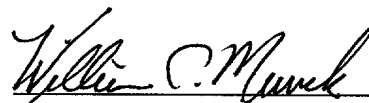
filed on July 15, 1992, now United States Patent No. 5,354,331 (the “‘486 Application”). The ‘830 Application also incorporated by reference the ‘486 Application, now United States Patent No. 5,354,331, into the body of the ‘830 Application.

The submitted substitute specification is derived from the specification of the foregoing line of United States patent applications. The submitted substitute specification is directed to teachings and inventions contemplated by the specifications of this line of United States patent applications. The submitted substitute specification is inherent to the same and no new subject matter has been included in the substitute specification.

The Applicant believes that this Application is in condition for allowance. If any outstanding issues remain, or if the Examiner has any further suggestions for expediting prosecution of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at [wmunck@novakov.com](mailto:wmunck@novakov.com).

Respectfully submitted,

NOVAKOV ♦ DAVIS, P.C.



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# Substitute Specification

ATTY. DOCKET NO. PRES06-00163

PATENT

## TECHNICAL FIELD OF THE INVENTION

This invention relates to methods of treating presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension and more particularly to methods of treating these diseases by increasing the effective working distance of the ciliary muscle. The invention also relates to increasing the amplitude of accommodation of the eye by increasing the effective working range of the ciliary muscle.

## BACKGROUND OF THE INVENTION

In order for the human eye to have clear vision of objects at different distances, the effective focal length must be adjusted to keep the image of the object sharply as possible on the retina. This change in focal length is known as accommodation and is accomplished by varying the shape of the crystalline lens. Generally, in an accommodated emmetropic eye the curvature of the lens is such that distant objects are sharply imaged on the retina. In the unaccommodated eye near objects are not focused sharply on the retina because their images lie behind the retinal surface. In order to visualize a near object clearly, the curvature of the crystalline lens is increased, thereby increasing its refractive power and causing the image of

the near object to fall on the retina.

The change in shape of the crystalline lens is accomplished by the action of certain muscles and structures within the eyeball or globe of the eye. The lens is located in the forward part of the, immediately behind the pupil. It has the shape of a classical biconvex optical lens, i.e., it has a generally circular cross section having two convex refracting surfaces, and is located generally on the optical axis of the eye, i.e., a straight line drawn from the center of the cornea to the macula in the retina at the posterior portion of the globe. In the unaccommodated human eye the curvature of the posterior surface of the lens, i.e., the surface adjacent to the vitreous body is somewhat greater than that of the anterior surface. The lens is closely surrounded by a membranous capsule that serves as an intermediate structure in the support and actuation of the lens. The lens and its capsule are suspended on the optical axis behind the pupil by a circular assembly of very many radially directed collagenous fibers, the zonules, which are attached at their inner ends to the lens capsule and at their outer ends to the ciliary body, a muscular ring of tissue located just within the outer supporting structure of the eye, the sclera. The ciliary body is relaxed in the unaccommodated eye and therefore assumes its largest diameter. According to the classical theory of accommodation, originating with Helmholtz, the

relatively large diameter of the ciliary body in this condition causes a tension on the zonules which in turn pull radially outward on the lens capsule, causing the equatorial diameter of the lens to increase slightly and decreasing the anterior-posterior dimension of the lens at the optical axis. Thus, the tension on the lens capsule causes the lens to assume a flattened state wherein the curvature of the anterior surface, and to some extent of the posterior surface, is less than it would be in the absence of the tension. In this state the refractive power of the lens is relatively low and the eye is focused for clear vision of distant objects.

When the eye is intended to be focused on a near object, the muscles of the ciliary body contract. According to the classical theory, this contraction causes the ciliary body to move forward and inward, thereby relaxing the outward pull of the zonules on the equator of the lens capsule. This reduced zonular tension allows the elastic capsule of the lens to contract causing an increase in the antero-posterior diameter of the lens (i.e., the lens becomes more spherical) resulting in an increase in the optical power of the lens. Because of topographical differences in the thickness of the lens capsule, the central anterior radius of curvature decreases more than the central posterior radius of curvature. This is the accommodated condition of the eye wherein the image of near

objects falls sharply on the retina.

Presbyopia is the universal decrease in the amplitude of accommodation that is typically observed in individuals over 40 years of age. In the person having normal vision, i.e., having emmetropic eyes, the ability to focus on near objects is gradually lost, and the individual comes to need glasses for tasks requiring near vision, such as reading.

According to the conventional view the amplitude of accommodation of the aging eye is decreased because of loss of elasticity of the lens capsule and/or sclerosis of the lens with age. Consequently, even though the radial tension on the zonules is relaxed by contraction of the muscles of the ciliary body, the lens does not assume a greater curvature. According to the conventional view, it is not possible by any treatment to restore the accommodative power to the presbyopic eye. The loss of elasticity of the lens and capsule is seen as irreversible, and the only solution to the problems presented by presbyopia is to use corrective lenses for close work, or bifocal lenses, if corrective lenses are also required for distant vision.

Certain rings have been used in ocular surgery for various purposes. Rings of flexible and/or elastic material, prepared in situ by fastening the ends of strips of the material around the generally posterior portion of the globe have been used to compress

the sclera in certain posterior regions. Supporting rings of metal, adapted to fit the contour of the sclera have been used as temporary supporting structures during surgery on the globe. However, none of these known devices have been used for surgical treatment of presbyopia, and none have been adapted to the special  
5 needs of prosthetic devices used in treating presbyopia.

Accordingly, a need has continued to exist for a method of treating presbyopia that will increase the amplitude of accommodation of the presbyopic eye, thereby lessening or  
10 eliminating the need for auxiliary spectacle lenses to relieve the problems of presbyopia.

SUMMARY OF THE INVENTION

A method of treating presbyopia and other eye disorders has now been found which comprises increasing the effective working distance of the ciliary muscle in the presbyopic eye.

5       Accordingly it is an object of the invention to provide a method for treating presbyopia.

A further object is to provide a method for treating presbyopia by increasing the effective working distance of the ciliary muscle in the presbyopic eye.

10       A further object is to provide a method for treating presbyopia by increasing the radial distance between the equator of the crystalline lens and the ciliary body.

15       A further object is to provide a method of treating presbyopia by suturing a scleral expansion band to the sclera of the globe at the location of the ciliary body.

A further object is to provide a method of treating presbyopia by weakening the sclera in the region of the ciliary body.

20       A further object is to provide a method of treating presbyopia by arresting the growth of the crystalline lens in the presbyopic eye.

A further object is to provide a method of treating presbyopia by shortening the zonules in the presbyopic eye.

A further object is to provide a method of treating presbyopia

by shortening the ciliary muscle or moving its insertions.

A further object is to provide a treatment for hyperopia.

A further object of the invention is to provide a treatment for primary open angle glaucoma.

5 A further object is to provide a treatment for ocular hypertension.

A further object is to provide a method for increasing the amplitude of accommodation of the eye.

10 Further objects of the invention will become apparent from the description of the invention which follows.



BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 shows an isometric view of a scleral expansion band of this invention;

FIGURE 2 shows an anterior elevational view of the band of  
5 FIGURE 1;

FIGURE 3 shows a posterior elevational view of the band of  
FIGURE 1;

FIGURE 4 shows a side view of the band of FIGURE 1.

FIGURE 5 shows a lateral sectional view of the band of  
10 FIGURE 2;

FIGURE 6 shows a posterior elevation view of another  
embodiment of the scleral expansion band of the invention which  
uses pins for fixation;

FIGURE 7 shows a lateral sectional view of the band of  
15 FIGURE 6;

FIGURE 8 shows a posterior elevation view of another  
embodiment of the scleral expansion band of the invention which  
uses tangentially extending fixation pins;

FIGURE 9 shows a lateral sectional view of the band of  
20 FIGURE 8;

FIGURE 10 shows a diagram of an exemplary laser of the type  
capable of treating various eye diseases in accordance with the  
principles of the present invention; and

FIGURE 11 shows an exemplary flow diagram of an exemplary method of operating a laser in accordance with the principles of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

This invention is based on a different theory, developed by the inventor, regarding the cause of the loss of amplitude of accommodation that constitutes presbyopia. According to this view, accommodation in the non-presbyopic eye is not due to relaxation of the lens and capsule when the zonular tension is relaxed as a result of the contraction of the ciliary body. On the contrary, the contraction of the ciliary body, exerts a tension on the zonular fibers that in turn actually results in an increase in the equatorial diameter of the lens. However, the increased zonular tension causes a decrease in the peripheral volume of the lens that in turn results in a corresponding increase in the central volume of the lens. These regional volume changes in the lens are responsible for the change in optical power of the lens. This view differs from all previous theories of the mechanism of accommodation and its loss in presbyopia, in particular from Tscherning's theory which required the vitreous and attributed presbyopia to an enlargement of the nucleus of the lens. From the inventor's point of view, the difference between the change in the central anterior radius of curvature and the change in the central posterior radius of curvature which occurs in accommodation is explained by the force distribution generated by the zonular attachment to the lens and is not dependent on the topographical

thickness of the elastic capsule of the lens, the vitreous, or pressure changes which occur between the anterior and posterior chambers, explanations which have been proposed in the prior art. According to the theory of this invention, presbyopia results when the distance between the ciliary body and the equator of the lens and its capsule becomes less with age as a result of the normal growth of the lens. The lens, being of ectodermal origin, continues to grow throughout life, albeit slowly. The rate of increase of the equatorial diameter is approximately 0.02 millimeters per year. On the other hand, the dimensions of the scleral shell of the eye, which is of mesodermal origin, do not increase significantly after about age 13 in a normally emmetropic, hyperopic or myopic eye. Consequently, the radial distance between the equator of the lens and capsule and the ciliary body, i.e., the distance measured perpendicularly to the optical axis in the plane of the ciliary body, decreases throughout life. It is well known in muscle physiology that as the length of the effective range of pull of a muscle, i.e., its effective working distance, is reduced, its effective force is reduced in a linear fashion. Since the distance between the ciliary body and the lens equator is decreasing throughout life, it is to be expected according to the theory of the invention that there would be a corresponding linear decrease in the amplitude of accommodation, as observed (Alpern, M., in The

Eye, H. Dayson, Ed., Academic Press, New York, 1969, pp. 237-238), which would lead eventually to presbyopia.

According to the invention presbyopia is treated by increasing the effective working distance of the ciliary muscle. A number of procedures are available to the surgeon which can accomplish this increase in effective working distance.

A straightforward method of increasing the effective working distance of the ciliary muscle is to increase the distance between the equator of the crystalline lens and the inner diameter of the ciliary body in the presbyopic eye. This increased distance restores, at least to some extent, the distance through which the muscles of the ciliary body can contract, and thereby restores their ability to exert force on the lens and change its shape to accomplish accommodation. Any method that increases the radial distance between the lens and the ciliary body is effective in the method of this invention.

The effective working distance of the ciliary muscle can also be increased by shortening the zonules that connect the ciliary muscle to the equator of the crystalline lens. Similarly, procedures that shorten the body of the ciliary muscle itself or move its insertions in the scleral spur and the choroid can be employed to increase the effective working distance of the muscle. Finally, procedures that arrest the growth of the lens can stop the

steady loss of amplitude of accommodation, and such procedures are considered as fully within the scope of this invention.

It is preferred to increase the lens-ciliary body radial distance by increasing the diameter of the sclera in the region of the ciliary body. Any method that can accomplish such an increase  
5 in the diameter of the sclera is considered to fall within the scope of the invention.

A preferred method of increasing the diameter of the sclera in the region of the ciliary body is to fasten to the sclera in that region a relatively rigid band having a diameter slightly larger  
10 than the section of the globe of the eye in the region of the ciliary body. In this way the sclera in that region is stretched and expanded so that the diameter of the circle describing the intersection of the plane of the ciliary body with the sclera is  
15 slightly increased. The ciliary body, located immediately inside the globe and attached to the sclera in this expanded region is thereby also increased in diameter.

Thus, the scleral expansion band of the invention adapted for fastening to the sclera of a human eyeball in the region of the  
20 ciliary body comprises an anterior rim and a posterior rim, the anterior rim being sized to lie adjacent to the anterior portion of a segment of the sclera of the human eyeball overlying the ciliary body of the eyeball and the posterior rim being sized to lie

adjacent the posterior portion of the scleral segment, and rigid structural means extending between the rims and spacing said rims apart so that the anterior rim will lie outside the anterior portion of the scleral segment when the posterior rim lies outside the posterior portion of said scleral segment. The anterior rim, the posterior rim and/or the rigid structural means connecting the rims has a diameter greater than the exterior diameter of the scleral segment adjacent thereto.

Thus, the scleral expansion band of the invention is adapted to be fitted to the sclera of the globe in the region of the ciliary body. The band will have, at least in part, a diameter slightly greater than that of the sclera at the location where it is to be attached. When the band is fitted to the sclera and firmly attached thereto it will exert a radially outward tension on the sclera which expands the sclera and the underlying ciliary body. The scleral expansion band of the invention may be fastened to the sclera by any conventional surgical method. For example, the band may be a smooth solid band and be sutured to the sclera with sutures passing around the body of the band. A preferred band of the invention is provided with suturing holes through which the sutures may be passed. The band may also be fastened with conventional surgical staples or clips as are well known in the ocular surgery art. The band may be provided with projections or

cut-out portions that can be used as anchoring points for sutures. The band may also be provided with projecting pins or the like which are inserted into or under the sclera to position the band and exert the appropriate radially outward tension. These pins may extend in an anterior and/or a posterior direction from the band, and may project from one or both rims of the band or from the web portion connecting the rims. The pins may also project in a generally tangential direction from the rims or the inside of the web and be provided with sharpened tips or the like whereby they will penetrate the sclera when the band is rotated and cause the sclera to be firmly fixed to the band and expanded. The band may also be adhesively fastened to the sclera with any physiologically acceptable surgical adhesive. A preferred surgical adhesive is a surgical grade cyanoacrylate adhesive. Mussel adhesive protein may also be used as a suitable adhesive.

A preferred embodiment of the scleral expansion band of the invention is illustrated in FIGS. 1-5. The band 102 has a low frustoconical shape and has a posterior rim 106 and an anterior rim 108, with a web 104 extending between the rims. The band may be provided with one or more holes 110 to assist in suturing the band to the sclera. The anterior rim 106 and the posterior rim 108 are both of generally circular shape. The taper in the diameter of the band is preferably selected in an individual case to fit the globe



in the region of the ciliary body. Accordingly, a preferred band has a low frustoconical having a circular base about 20 millimeters in diameter. The radial thickness of the band will be determined by the rigidity required in the band and the strength of the material from which it is made. Typically the radial thickness of the band will be about 0.1 to 0.75 millimeters depending on the rigidity of the substance used to make the band. The diameter of the anterior rim 106 of the band will be determined by the size of the globe in the patient to be treated. Accordingly, different sizes of band are available wherein the lesser diameter ranges from about 14.5 millimeters to about 18.0 millimeters in 0.25 millimeter increments. The axial width of the band will typically be about 2 millimeters.

An alternate embodiment of the scleral expansion band of the invention adapted to be fixed to the sclera by pins is illustrated in FIGS. 6 and 7. In this embodiment posterior pins 112 are fixed to the band and extend therefrom in a posterior direction while anterior pins 114 extend in an anterior direction.

Another embodiment of the band of the invention using interior tangentially-directed pins 114 is illustrated in FIGS. 8 and 9. This embodiment can be easily installed by placing it in position on the globe and rotating it to cause the tangential pins to penetrate the sclera and fasten it firmly to the band. This

embodiment can be easily removed at a later time by merely rotating it in the opposite direction to withdraw the pins from the sclera.

The scleral expansion band of the invention is made of a material that is sufficiently rigid to exert a force on the sclera sufficient to produce the radial expansion required by the method of the invention and that is physiologically acceptable for long-term implantation or contact with the ocular tissues. Such materials are well-known in the surgical art and include suitable metals, ceramics, and synthetic resins. Suitable metals include titanium, gold, platinum, stainless steel, tantalum and various surgically acceptable alloys, and the like. Suitable ceramics may include crystalline and vitreous materials such as porcelain, alumina, silica, silicon carbide, high-strength glasses and the like. Suitable synthetic resins include physiologically inert materials such as poly(methyl methacrylate), polyethylene, polypropylene, poly(tetrafluoroethylene), silicone resins and the like. The band may also be made of composite materials incorporating a synthetic resin or other matrix reinforced with fibers of high strength material such as glass fibers, boron fibers, carbon fibers, alumina fibers or the like. Thus, the band may be made of glass-fiber-reinforced epoxy resin, carbon fiber reinforced epoxy resin, carbon fiber reinforced carbon (carbon-carbon), or the like. A preferred material is surgical grade

poly(methyl methacrylate).

The scleral expansion band of the invention may be manufactured by any conventional technique appropriate to the material used, such as machining, injection molding, heat molding and the like.

The scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band. The band may be adjustable in circumference. For example the band may be formed from a strip of material, e.g., metal or synthetic resin, with overlapping ends so that the ends may slide past one another thereby adjusting the circumference of the band. The length of the overlap may be adjusted, for example, by means of a tangential screw mechanism to adjust the circumference of the band and thereby the amount by which the sclera is expanded.

In practicing the method of the invention, the surgeon locates the proper region of the sclera to be expanded by measuring a distance of 1.5 millimeters posterior of the limbus. At this point the diameter of the circle of sclera surrounding the ciliary body is carefully measured and a band is selected having a minor diameter about 0.5 millimeter greater than the measured diameter. A circular incision is made through the conjunctiva completely around the globe at the selected region and the conjunctiva and

Tenon's capsule are reflected to expose the substance of the sclera. For greatest accuracy in positioning the scleral expansion band, the diameter of the sclera as exposed by the reflection of the conjunctiva and Tenon's capsule is measured at a point 1.5 mm  
5 posterior to the limbus. Alternatively the size of sclera can be measured before the conjunctiva is incised. The band is then placed on the surface of the globe and sutured thereto preferably with interrupted stitches as conventional in ophthalmological surgery. In order to facilitate suturing the band to the sclera, the band  
10 may be perforated with holes. For example, a total of sixteen holes may be placed equidistant around the band.

It is also possible to expand the sclera in the region of the ciliary body by positioning a band within or just inside the sclera, the band having a diameter just greater than the natural  
15 diameter of the overlying tissue. In this way the interior band will expand the overlying tissue and produce the desired result of increasing the effective working distance of the ciliary muscle.

Other methods for increasing the diameter of the sclera in the region of the ciliary body may also be used in the treatment of  
20 presbyopia according to the invention. The sclera itself is a tough strong capsule comprised largely of collagen and held in a rigid state of tension by the internal ocular pressure (IOP). If the sclera is weakened in the area adjacent to the ciliary body, the

IOP will cause that portion of the sclera to bulge outward, thereby increasing the diameter of the ciliary body and increasing the distance of the ciliary body from the lens. Any method of weakening the structure of the sclera is suitable. For example enzymatic degradation of the collagen by collagenase may be employed. The collagenase may be carefully injected in to the appropriate region of the sclera or may be applied topically. Equivalent enzymes or other chemical treatments that weaken the collagen of the sclera can also be used. Certain antimitotic drugs such as mitomycin are known to cause a softening of the sclera (scleromalacia), and these drugs can be applied to the region of the sclera adjacent to the ciliary body, either topically or by injection, to effect the desired weakening of the sclera. Other antimitotic pharmaceutical agents, e.g., methotrexate, azaribine, 6-mercaptopurine, 5-fluorouracil, daunorubicin, doxorubicin, cytarabine, the vinca alkaloids and the like, can also be applied to the sclera to weaken it and permit it to be expanded by the intraocular pressure.

Alternatively, the sclera in the region of the ciliary body may be weakened by surgical means.

The sclera may be thinned or weakened by the surgical removal of a portion of its collagenous substance, as, for example by ablating a portion of the thickness of the sclera. This thinning can be accomplished by paring or by abrading the surface or by

ablating the surface with laser irradiation. The sclera can also be weakened by incisions carefully placed at appropriate angles in the region overlying the ciliary body. The diameter of the sclera overlying the ciliary body can also be increased by making a complete periglobular incision and grafting into the incision appropriate tissue and/or physiologically acceptable structural material to increase the dimensions of the sclera. Thus an artificial scleral alloplant made of purified human collagen may be engrafted into such an incision. Other known biocompatible materials, e.g., poly(ethylene terephthalate), that are conventionally used in the construction of prosthetic devices may also be used for engrafting into such an incision. It is also possible to excise a small strip of sclera from the region overlying the ciliary body and replace it with a scleral alloplant as described above to provide an appropriate increase in the diameter of this region.

FIGURE 10 shows a diagram of an exemplary laser 1000 of the type capable of treating various eye diseases in accordance with the principles of the present invention. Such eye diseases include presbyopia, hyperopia, primary open angle glaucoma, and ocular hypertension. Laser 1000 may be any suitably arranged laser, for instance, any of a carbon dioxide laser, a helium-neon laser, a helium-cadmium laser, an argon ion laser, a krypton ion laser, a

5 xenon laser, a nitrous oxide laser, iodine laser, a holmium doped yttrium-aluminum garnet laser, an excimer laser, a chemical laser, a harmonically oscillated laser, a dye laser, a nitrogen laser, a neodymium laser, an erbium laser, a ruby laser, a titanium-sapphire laser and a diode laser.

10 Laser 1000 is operable to weaken the sclera of an eye in the region of the ciliary body to thereby increase the effective working distance of the ciliary muscle of the eye and increase the amplitude of accommodation of the eye, all in accordance with the principles of the present invention.

15 Exemplary laser 1000 illustratively includes a power supply 1010, laser beam generator 1020 and a controller 1030. Exemplary power supply 1010 supplies power to laser 1000. Exemplary laser beam generator 1020 is operable to generate a narrow coherent beam of radiation. Exemplary controller 1030 is operable to control the intensity of the laser beam generated. The laser beam may be one of ionizing radiation or non-ionizing radiation.

20 Laser 1000 is operable to weaken the sclera of the eye in the region of the ciliary body, for instance, by (i) abrading the sclera with laser irradiation, (ii) ablating the sclera with laser irradiation, (iii) incising the sclera with laser irradiation, (iv) incising the sclera at select angles with laser irradiation, and (v) decomposing partially collagen fibers in the sclera.

Exemplary laser 1000 is illustrated with three stages. Exemplary stage 1: in a laser, energy is stored in a "lasing" medium, which may be a solid, liquid or gas; the energy excites atoms in the medium, raising them to a high-energy state such that an excited atom releases a light ray (here, electrons in an electric current excite the gas atoms). Exemplary Stage 2: a ray of light from the excited atom strikes another excited atom, causing it also to emit a light ray; these light rays strike more excited atoms, and the process of light production grows, such that mirrors at the ends of the tube reflect the light rays so that more and more excited atoms release light. Exemplary Stage 3: as each excited atom emits a light ray, the new ray vibrates in step with the ray that strikes the atom; all the rays are in step, and the beam becomes bright enough to pass through the semi-silvered mirror and leave the laser; the energy is as laser light.

Turning to FIGURE 11, shown is an exemplary flow diagram (generally designated 1100) of an exemplary method of operating a laser in accordance with the principles of the present invention. The discussion of FIGURE 11 is made concurrently with reference to FIGURE 10 and laser 1000.

Exemplary method 1100 operates laser 1000 to treat presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension. Initially laser 1000 is enabled, causing laser beam generator 1020



to generate a laser beam whose intensity is controlled by controller 1030 (process step 1110). Laser 1000 is used to irradiate the sclera of an eye in the region of the ciliary body in accordance with the principles of the present invention to thereby  
5 weaken the sclera of the eye and to increase the effective working distance of the ciliary muscle of the eye (Step 1120).

This step of irradiating the sclera of an eye in the region of the ciliary body may comprise (i) abrading the sclera with laser irradiation; (ii) ablating the sclera with laser irradiation;  
10 (iii) incising the sclera with laser irradiation (including at select angles); and (iv) decomposing partially collagen fibers in the sclera.

Any irradiative treatment with ionizing or non-ionizing radiation that weakens the sclera may be used. For example  
15 irradiation with electrons, protons, or x-rays and the like, or irradiation with ultrasonic waves or the like can be used. Thermal burning and/or scarring in the appropriate area may also be used to induce an enlargement of the sclera in the area adjacent to the ciliary body.

20 Treatments designed to weaken the sclera in the region overlying the ciliary body can also be combined with application of the scleral expansion band of the invention. For example, the sclera can be treated with collagenase, mitomycin, or other

antimitotic agent, as described above and the scleral band subsequently applied and fastened to the sclera. The band itself, its components and/or the sutures may also be coated or impregnated with the sclera-weakening agents whereby they can come into contact with the sclera and exercise their effect when the band is applied. In some cases the band may be later removed to leave the patient with a suitably expanded sclera.

Just as the distance between the ciliary body and the equator of the lens can be increased by expanding the sclera and ciliary body, the distance can be maintained and the progress of presbyopia arrested by stopping the growth of the crystalline lens. While such a treatment cannot reverse the course of presbyopia, it can arrest the progress of the symptoms, and is appropriate for treatment of patients in whom the presbyopia has not progressed very far. The growth of the lens can be arrested by administration of pharmaceutical compounds which stop cell division and growth. For example, colchicine can be administered to prevent cell division, thereby stopping the growth of the lens. Conventional antimitotic drugs may also be used to arrest the growth of the lens. Such drugs are well known and include, for example, methotrexate, azaribine, 6-mercaptopurine, 5-fluorouracil, daunorubicin, doxorubicin, cytarabine, the vinca alkaloids and the like. Such drugs may be applied topically or by injection into the appropriate structure of

the eye where they will come into contact with the lens and exercise their pharmacological activity. If the drugs are sufficiently free of side effects, they may also be administered systemically, either by mouth or parenterally. The growth of the lens may also be arrested by physical treatments directed at the newly forming cells in the epithelium of the lens, particularly in the equatorial region of the lens. Treatments that prevent further division of the cells are appropriate for preventing further lens growth. Thus, the epithelial cells may be heated by laser radiation or ultrasonic irradiation, or inactivated by laser irradiation with a laser capable of directly disrupting chemical bonds within the structures of the cells. Sharply focused laser beams or irradiation with microscopic diode lasers positioned close to the equator of the lens are suitable for applying this radiation. Irradiation with electrons, protons, x-rays or the like may also be used to stop the further division of the epithelial cells of the lens. These treatments should be directed only to the portion of the lens structures that are composed of cells capable of dividing and should not be directed toward the substance of the lens where they might provoke the formation of cataracts.

Surgical methods that work more directly on the ciliary muscle may also be used to increase the effective working distance of the muscle. The body of the muscle itself may be shortened, for example

by scarring induced by irradiation with suitable laser beams or beams of ionizing or non-ionizing radiation such as ultrasound or electron or proton beams or x-rays. The effective working range of the muscle may also be increased by moving its insertions to  
5 increase the distance between them. The ciliary muscle is inserted anteriorly into the scleral spur and posteriorly into the choroid. Treatment of either of these insertions to cause them to move apart from the complementary insertion will increase the effective working range of the ciliary muscle and improve the amplitude of  
10 accommodation according to the invention. Selective scarring of adjacent tissue planned to cause retraction of either insertion of the ciliary muscle is effective to accomplish this result. The scarring can be accomplished by thermal or radiative treatment of the tissue by the means and methods generally outlined above.

15 The method of the invention which increase the amplitude of accommodation may also be of benefit in treatment of hyperopia in certain patients. Some youthful hyperopes can achieve relatively normal vision by compensating for their hyperopia through the natural accommodative ability of the eye. However, as this ability  
20 declines with age, they find that it becomes more difficult to attain normal vision by this process, and they begin to experience headaches and other symptoms, even at an age somewhat less than usual for the onset of presbyopia. Evidently, increasing the

amplitude of accommodation by the method of this invention would be useful in restoring the ability of these patients to compensate for their hyperopia.

The method of this invention also has utility in the treatment  
5 of primary open-angle glaucoma, which shows a correlation with age  
in certain individuals. It has been found that, in general, IOP  
exhibits a linear increase with increasing age. (Armaly, M.F., On  
the distribution of appplanation pressure I. Statistical features  
and the effect of age, sex, and family history of glaucoma,  
10 Archives of Ophthalmology, Vol. 73, pp. 11-18 (1965).) Among the  
general population is found a group of individuals who develop  
abnormally high intraocular pressures as a result of primary open  
angle glaucoma, a disease which is one of the most prevalent causes  
of blindness in the world. According to the theory of this  
15 invention, the linear increase in IOP with age is a direct result  
of the decrease in distance between the lens equator and the  
ciliary muscle and the resulting linear decrease in the effective  
pull of the ciliary muscle. Since the ciliary muscle inserts into  
the trabecular meshwork, the decrease in pull will decrease the  
20 size of the trabeculum and/or the drainage pores and result in a  
linear increase of intraocular pressure with age. In this view, the  
patients who develop primary open angle glaucoma may have a  
congenital predilection to narrower pores and/or smaller trabecular

meshwork, so that when the ability of the ciliary muscle to exert force declines, after the age of 40 or thereabouts, they tend to develop excessively elevated IOP.

5 The method of the invention which increases the effective working distance of the ciliary muscle, and thereby increases the force that it can exert when it contracts, restores the level of force which the ciliary muscle exerts on the trabecular meshwork to a value characteristic of a more youthful eye. In this way it is expected that the tendency of an eye that is disposed to develop  
10 primary open angle glaucoma as it ages would be overcome and the onset of this disease would be prevented or at least postponed.

15 The ability of the ciliary muscle to exert tension on the lens by means of the zonules can also be increased by shortening the zonules, a procedure which increases the effective working range of the ciliary muscle. This shortening can be produced by heating the zonules by ultrasonic irradiation or laser irradiation. The zonules may also be treated with electrons, protons, x-rays and the like which may cause changes in the structure of the zonules resulting in shortening. The shortening of the zonules may also be brought  
20 about by application of chemical compounds that act to cause a shrinkage of the collagenous zonules.

The invention will be illustrated by the following examples which are intended for illustration only and are not to be

interpreted as limiting the claims.

EXAMPLE 1

This example illustrates the feasibility of increasing the  
5 diameter of the ciliary body by suturing an external band to the  
sclera.

Human cadaver eyes were selected for experimentation. The  
diameter of the sclera was measured using a shadow graph at  
distances of 1.5 millimeters and 3.5 millimeters from the limbus.  
10 The diameters were found to be 16.2 mm and 20 mm respectively.  
Bands were made from medical grade poly(methyl methacrylate) having  
a low frustoconical shape and a radial thickness of 0.5 mm. The  
internal diameter of the larger (posterior) side was 20 mm, and the  
smaller (anterior) diameters varied from 14.5 mm to 18.0 mm in 0.25  
15 mm steps. A band was selected having a major diameter of 20 mm and  
a minor diameter of 18.0 mm. The band was placed on the sclera of  
a human cadaver eye so that the 18.0 mm diameter end of the band  
was 1.5 mm from the limbus and the 20 mm diameter end was 3.5 mm  
from the limbus. The band was sutured through the holes with 16  
20 interrupted 6-0 polyester (Mersilene, Ethicon, Inc.) stitches to  
the sclera. This resulted in a clearly observable stretching of the  
sclera in the region of the ciliary body. The pupil became dilated  
by about 1.5 mm. Since the iris inserts into the ciliary body, the

pupillary dilation demonstrated that the induced scleral stretching was also moving the ciliary body outward, thereby increasing its diameter and its distance from the equator of the lens.

5     EXAMPLE 2

        This example illustrates the treatment of presbyopia in patients.

        Following informed consent, six presbyopic patients with otherwise normal eyes, except for minimal refractive errors, had  
10     scleral expansion bands of the invention sutured to the sclera in the region of the ciliary body. Their age ranged from 47 to 60 years, there were three males and three females, and their preoperative amplitude of accommodation varied from 1.3 to 2.7  
15     diopters. The ophthalmological examination including biomicroscopy was normal. Following local infiltration into the conjunctive with prilocaine HCl for injection (Citanast (Astra), 40 mg/ml), a 360 degree limbal based peritomy was performed and the sclera was  
20     cleaned of Tenon's capsule. Using vernier calipers, a distance of 1.5 mm posterior to the limbus was measured from the limbus and the scleral diameter was measured at that location. A band of the type made in Example 1 was selected having a minor diameter of from 0.5 mm to 1.5 mm greater than the measured diameter of the sclera. The band was sutured to the sclera with 16 interrupted 6-0 polyester



(Mersilene, Ethicon, Inc.) stitches. The patients were given antibiotic-steroid drops to use for five days. Postoperatively, the patients were followed daily for five days and then weekly. The results are presented in Table 1 below.

TABLE 1

## Preoperative and Postoperative Amplitude of Accommodation

Patient No.	Age (yr)	Sex	Preoperative		Postoperative	
			Near Point (cm)	Amplitude of Accommodation (diopters)	Near Point (cm)	Amplitude of Accommodation (diopters)
1	55	M	75	1.3	9	11.1
2	50	F	45	2.2	10	10.0
3	47	F	37	2.7	16	6.25
4	56	M	56	1.7	9	11.1
5	60	F	38	2.6	12	8.3
6	46	M	40	2.5	17	5.8

The invention having now been fully described, it should be understood that it may be embodied in other specific forms or variations without departing from its spirit or essential characteristics. Accordingly, the embodiments described above are to be considered in all respects as illustrative and not

restrictive, the scope of the invention being indicated by the appended claims rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are intended to be embraced therein.

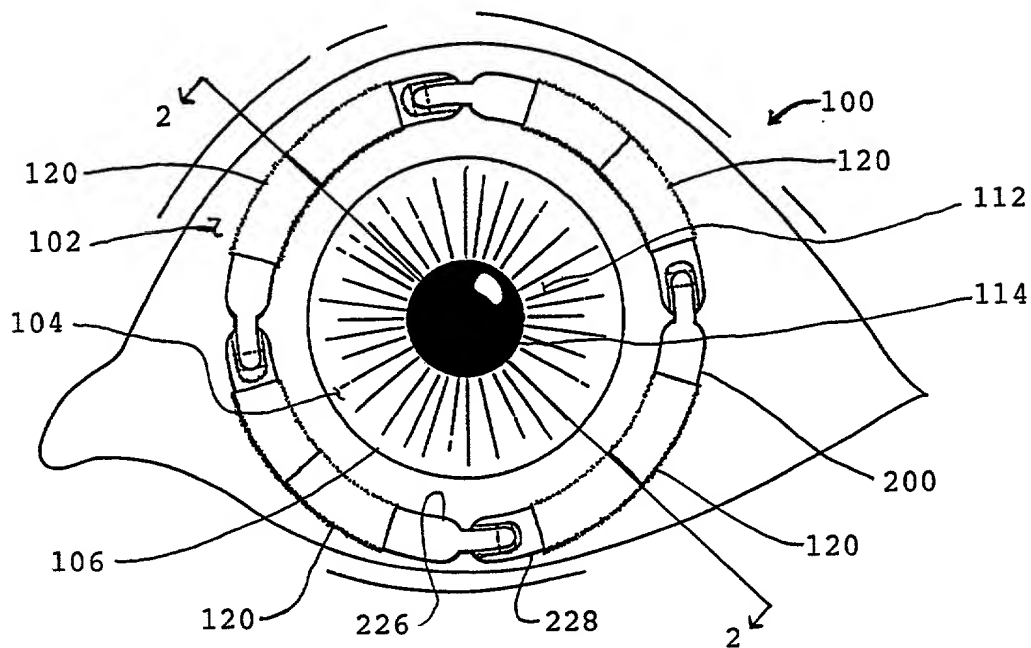
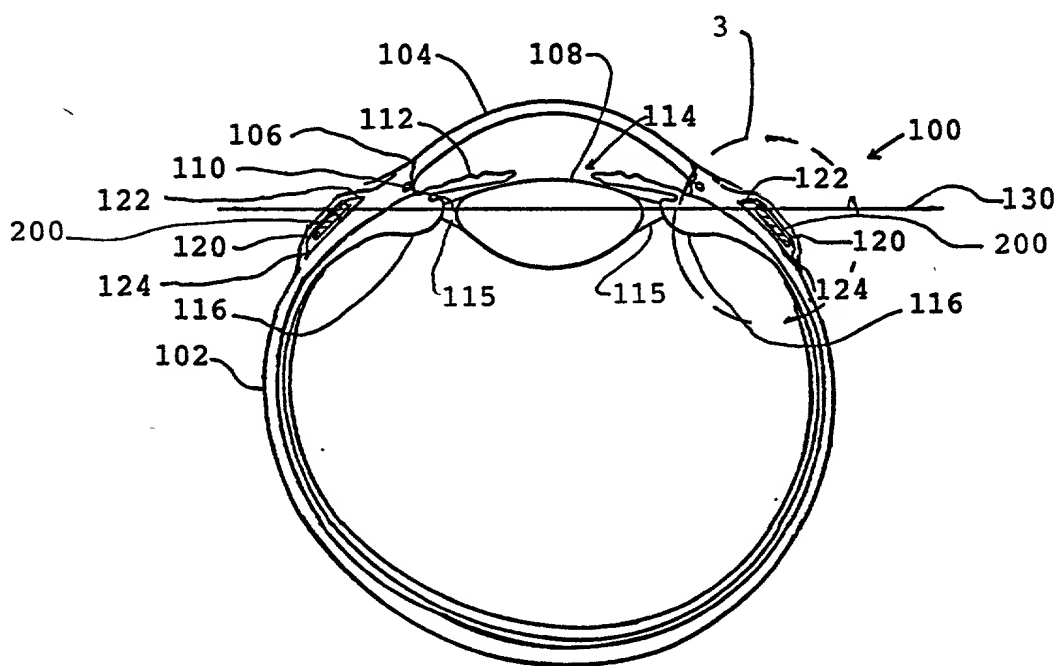


Fig. 1



**Fig. 2**

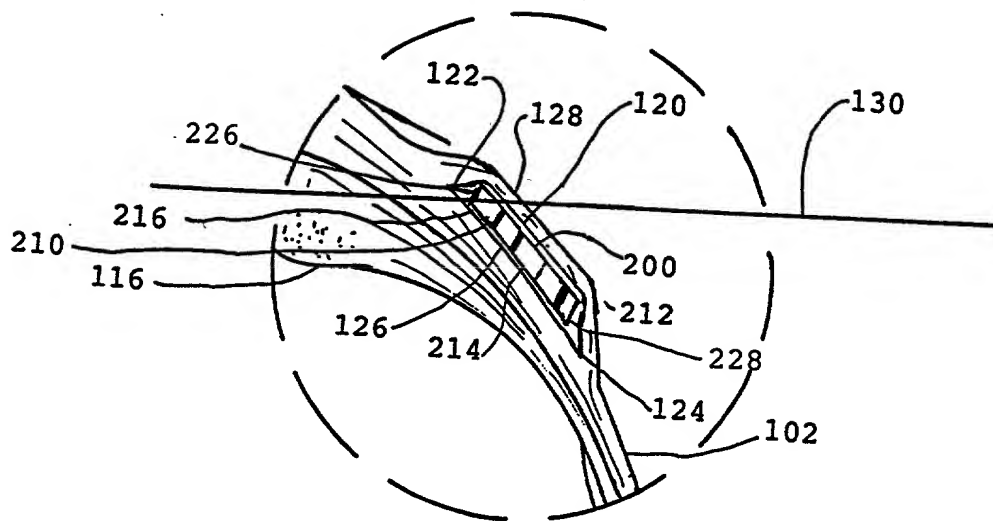


Fig. 3

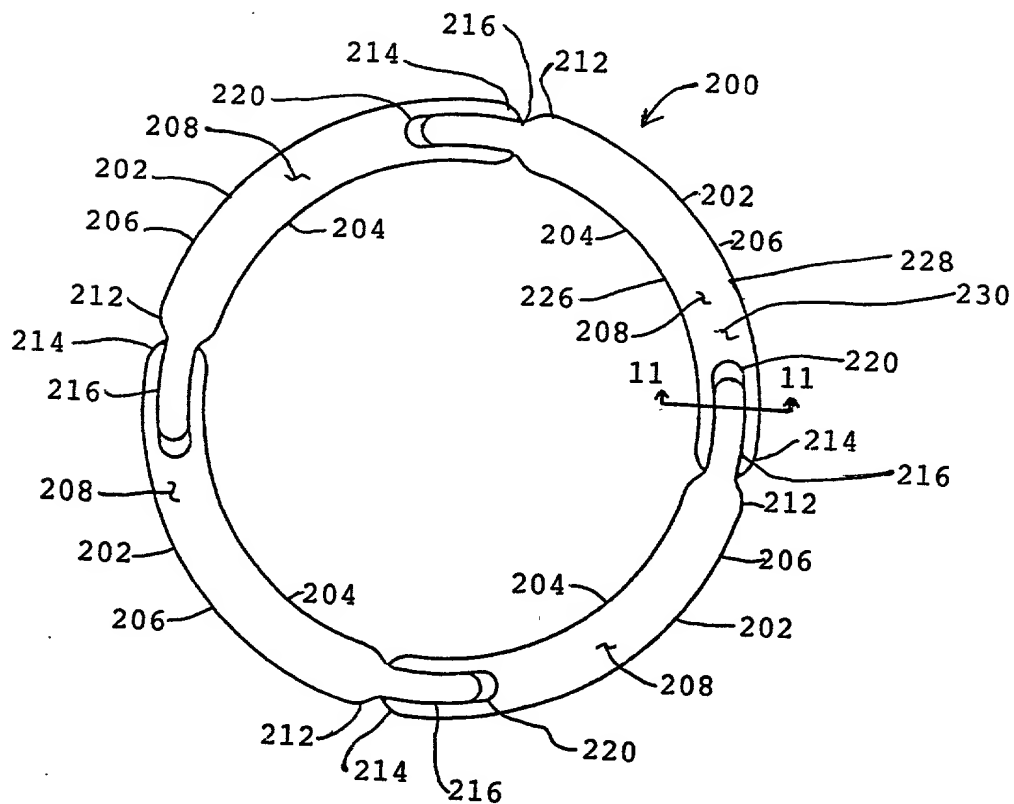


Fig. 4

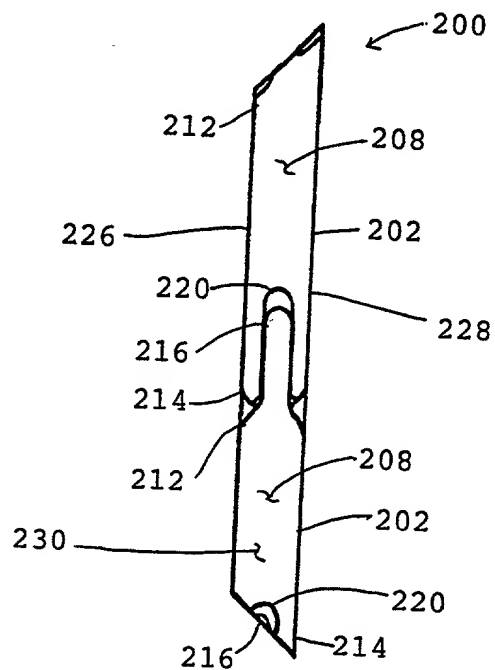


Fig. 5

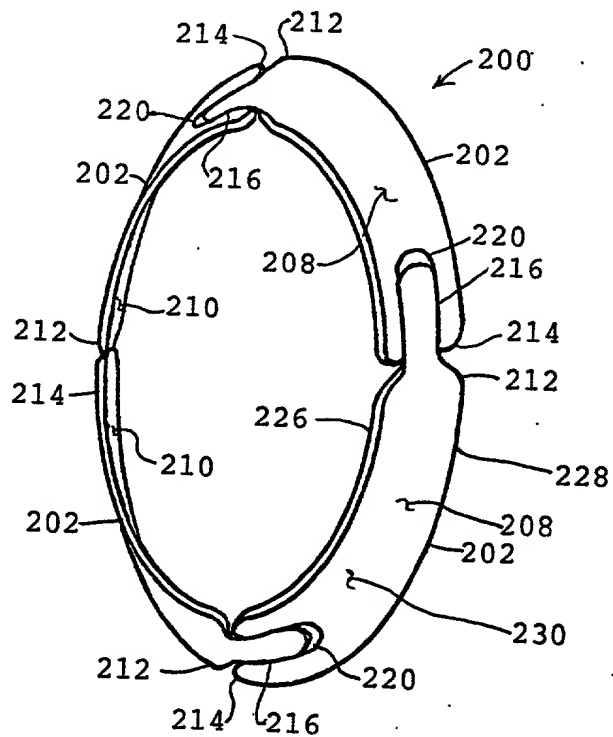


Fig. 6

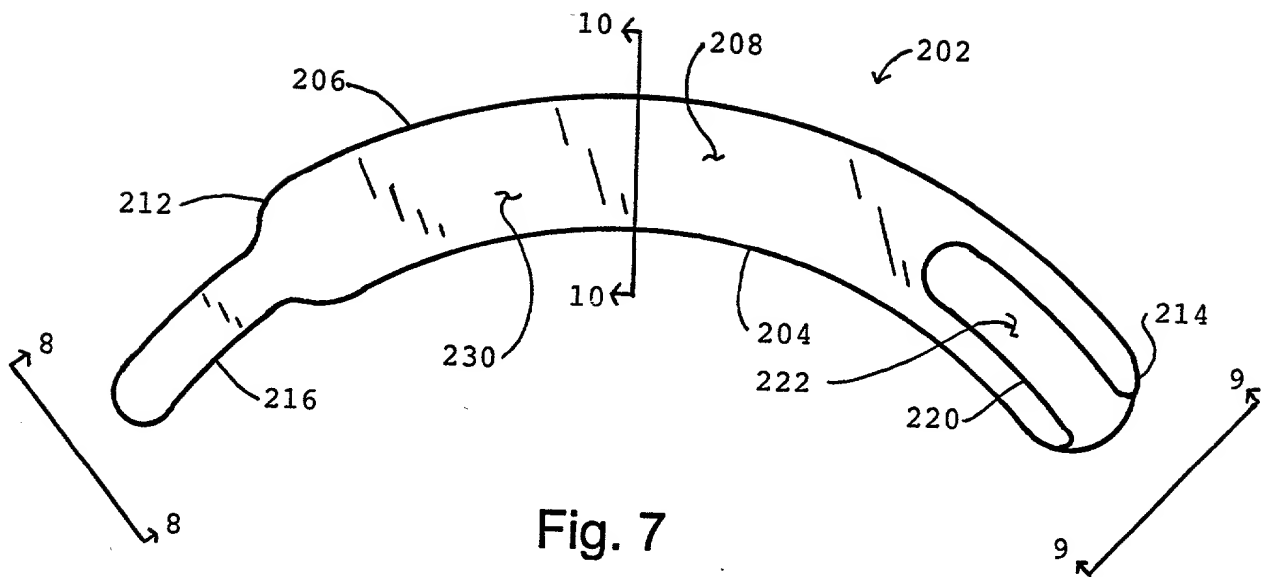


Fig. 7

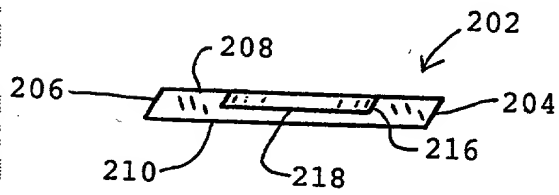


Fig. 8

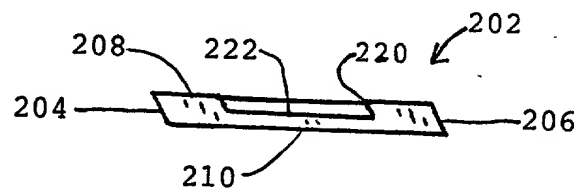


Fig. 9

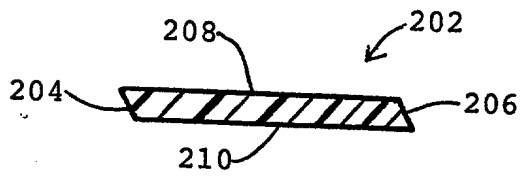


Fig. 10

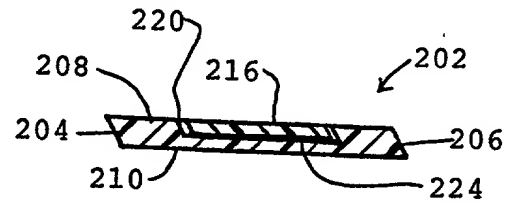
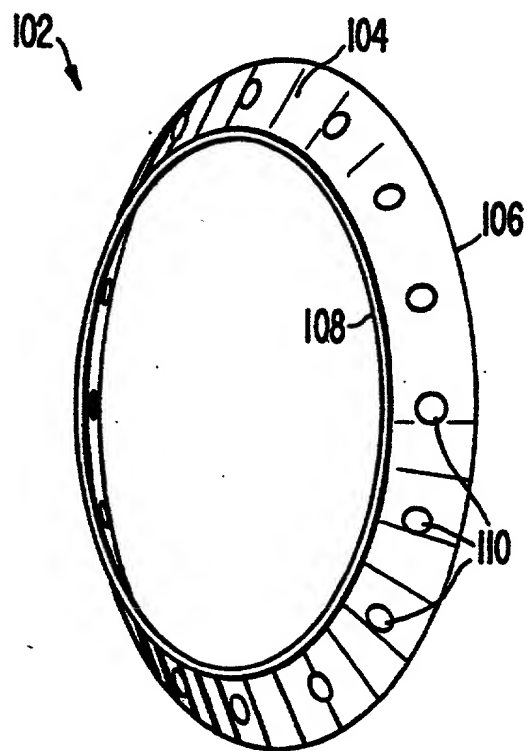
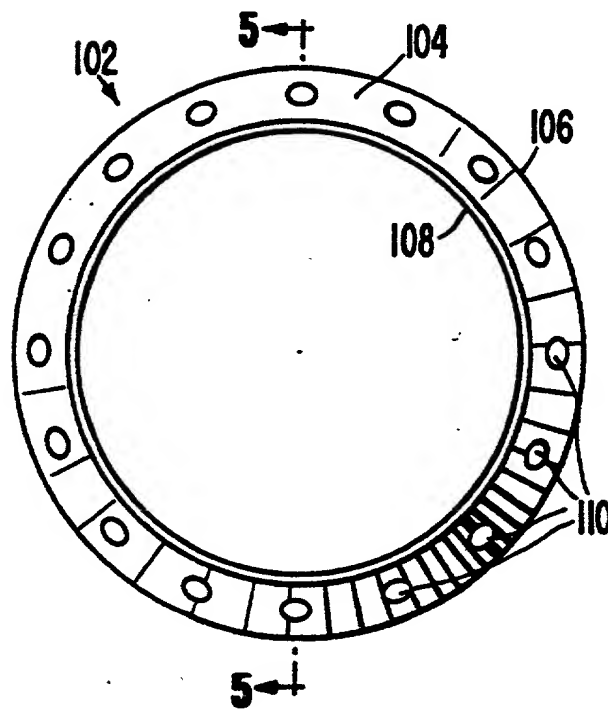


Fig. 11

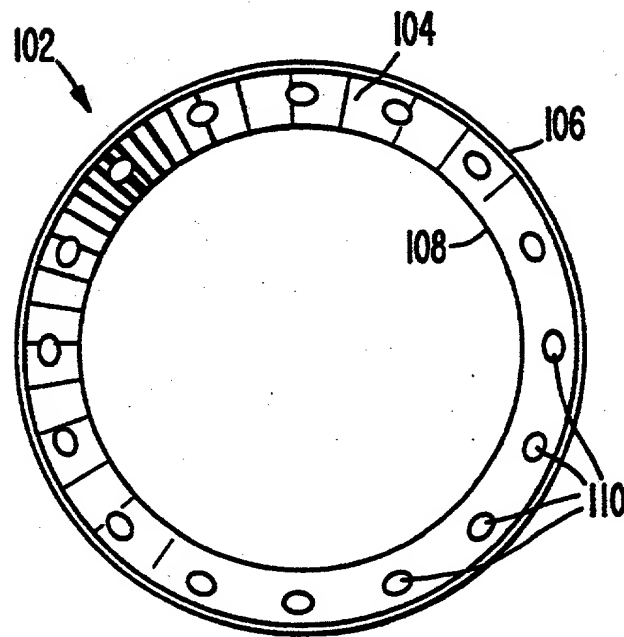
**FIG. 1**



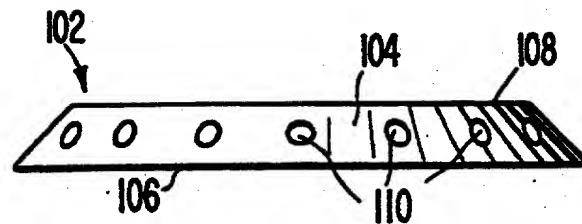
**FIG. 2**



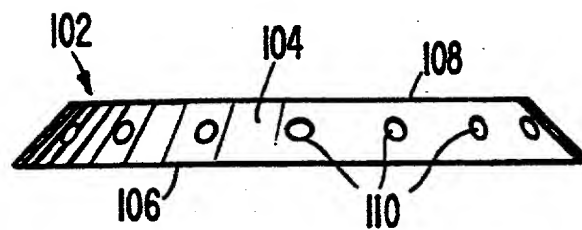
**FIG. 3**



**FIG. 4**

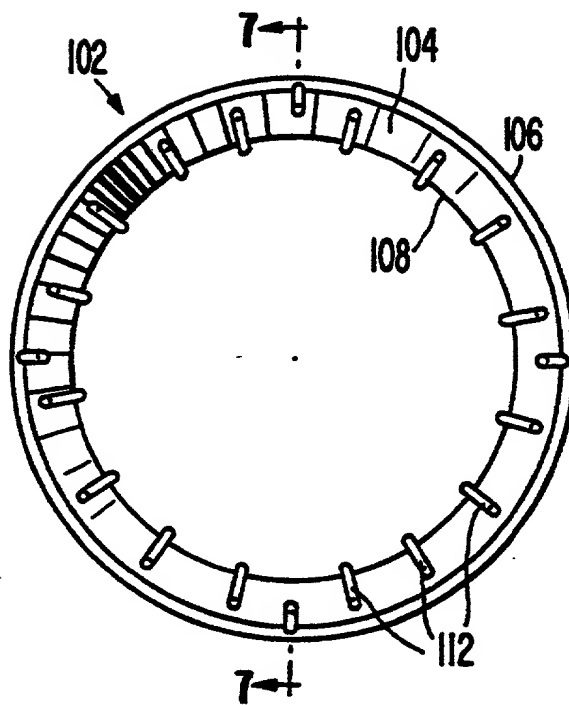


**FIG. 5**

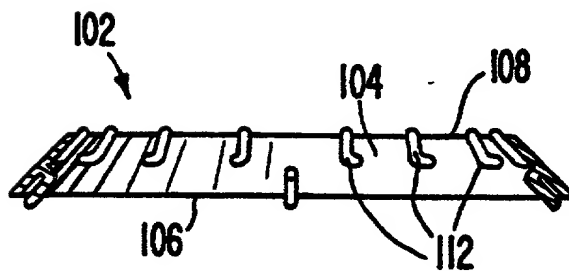




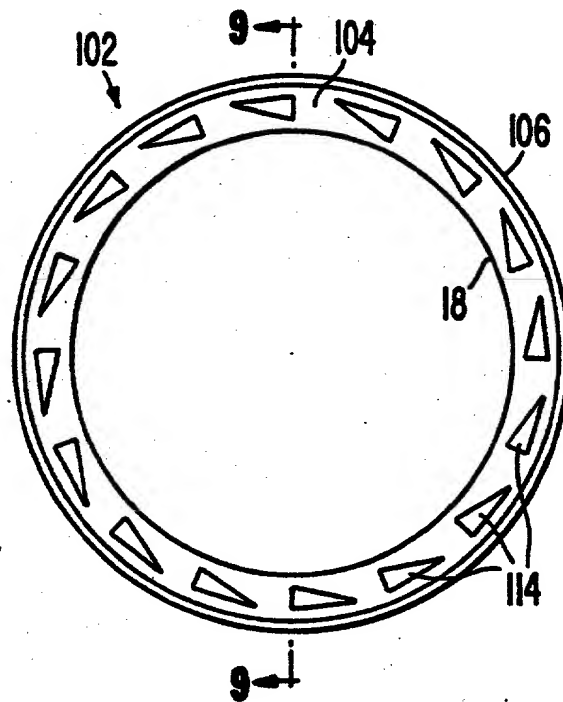
**FIG. 6**



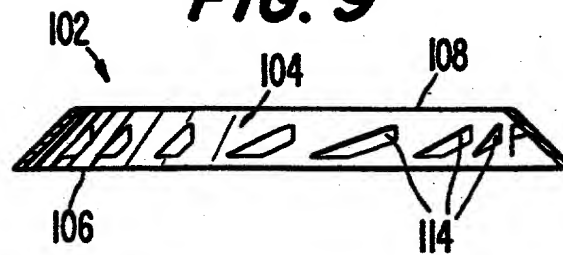
**FIG. 7**



**FIG. 8**



**FIG. 9**



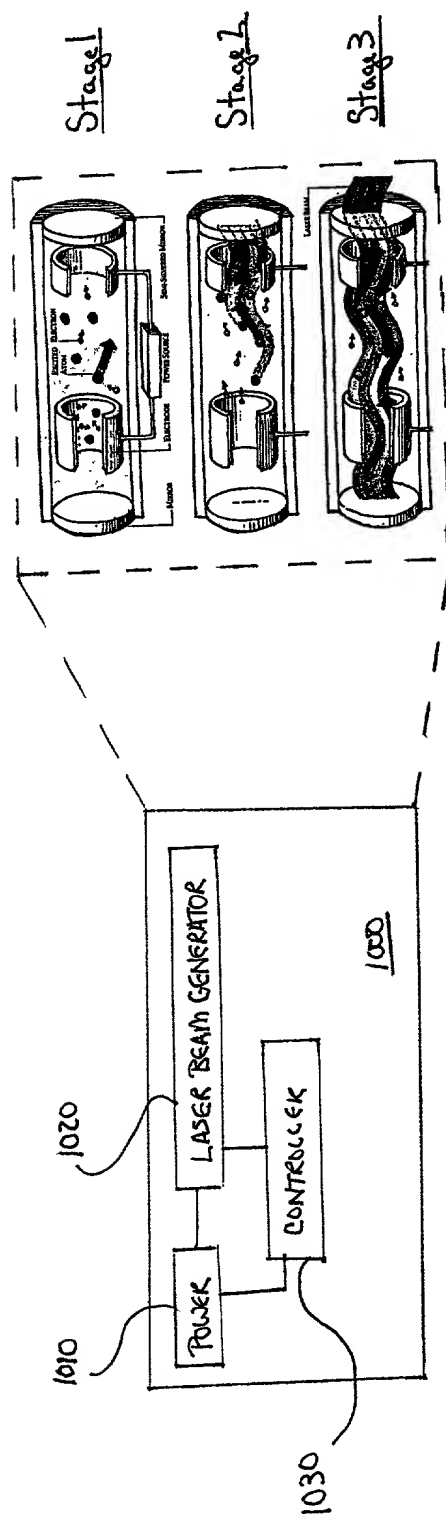


Figure 10

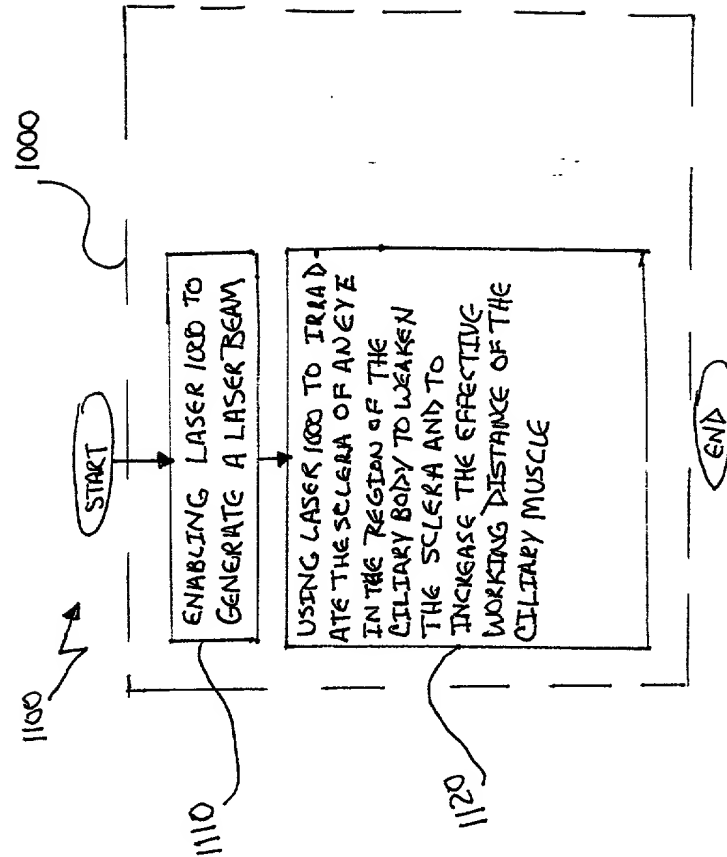


Figure 11

# COPY

DOCKET NO. PRES06-00022  
(formerly 13938-00009)

PATENT

## DECLARATION AND POWER OF ATTORNEY

As the below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention, design or discovery entitled:

- **SEGMENTED SCLERAL BAND FOR TREATMENT OF PRESBYOPIA  
AND OTHER EYE DISORDERS**

the specification of which was filed and assigned U.S. Serial No. 09/032,830 on March 2, 1998.

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the Office all information known to me to be material to the patentability of this application as defined by Title 37, Code of Federal Regulations, § 1.56.

I hereby claim no foreign priority benefits under 35 U.S.C. § 119 of any foreign application(s) for patent or inventor's certificate on which priority is claimed.

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in § 1.56 which became available between the filing date of any prior application(s) and the national or PCT international filing date of this application.

APPLICATION SERIAL NO.	DATE FILED	STATUS
08/462,649	June 5, 1995	patented, U.S. 5,722,952
08/139,756	October 22, 1993	patented, U.S. 5,489,299
07/913,486	July 15, 1992	patented, U.S. 5,354,331

COPY

I hereby appoint:

William A. Munck, Registration No. 39,308  
John T. Mockler, Registration No. 39,775

all of the firm of NOVAKOV, DAVIDSON & FLYNN, P.C. my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith, and to file and prosecute any international patent applications filed thereon before any international authorities under the Patent Cooperation Treaty.

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Atty. Docket No.: PRES06-00022

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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